

DETAILED ACTION

Applicants set of remarks filed on 5 October 2011 has been acknowledged and duly made of record.

Response to Arguments

Essentially, applicants' argue that the references of record are improper for failing to disclose a formulation of DHA: EPA for human that is an adult.

Applicants' argument is considered but is not found persuasive. The fact that a formulation consisting of DHA:EPA has been established in the art as a formulation drawn to infants still does not preclude the use by humans that are adults especially if the doses are increased which would reasonably be too toxic for a human infant. Further, the fact that O'Connor teaches '*catch-up*' *feeding regimens* to increase calorie intake and prevent growth inhibition still does not preclude the formulation being a viable treatment for obesity or an overweight condition. It is well-established in nutritional paradigms that a well-balanced diet consisting of *proper fats*, nutrients, and minerals can be effective in preventing *inter alia* obesity.

Applicants have amended the claim to read on a human who is an adult but the one of pertinent skill in the art would clearly recognize that based upon an optimization of the ratio of DHA: EPA, an adult dose drawn to infant formula could be readily envisioned.

Breivik was specifically employed in order to encompass a human who is an adult by disclosing an adult population between the ages of 34-60. Further, the fact that Breivik cites that the adult population is "not extremely overweight" still does not preclude Breivik from still being obvious over claim 13. In other words, the patients of Breivik could still be obese, have an overweight condition, need weight reduction, etc.

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Corkey was employed to a formulation comprising a dairy supplement to reduce fat content in adult patients. Applicants assert that the teachings of O'Connor contradict the scope of Corkey and therefore is improper in obviousness over the claimed invention.

Applicants' arguments are considered but are not found persuasive because:

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, as has been explained above, biological parameters differ between an infant and a human adult. The fact that O'Connor teach a formulation drawn to infants does not preclude this formulation from being optimized for adult consumption based upon the reasoning of Breivik and Corkey.

For the reasons already made of record, the rejection of record is hereby maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 15-22, 37, 39-46, 49-55, 57-58, and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al. (USPN6,596,302 B2) and Breivik et al. (USPN 5,502,077) in view of Corkey et al.

O'Connor et al. teach in column 19 at line 16 a DHA: EPA ratio preferably at least 3:1.

O'Connor et al. teach in the instant abstract [m]ethods for providing nutrition and for enhancing neurological development of preterm infants are disclosed. Also disclosed is an improved nutritional composition containing specified amounts of DHA and AA as well as their precursor essential fatty acids alpha-linolenic and linoleic acids. The methods involve feeding LCP supplemented, nutrient-enriched formulas for an extended feeding regimen, typically until

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at least 3 months corrected age (CA), preferably to 6 or even 12 months CA. The neurological developments, for example, visual development, motor development and language development were enhanced without findings of anthropometric growth faltering or inhibition. Thus, based upon the current abstract, the limitations of claim 13 are also hereby encompassed as the one of skill would reasonably expect formulations for infants containing DHA:EPA to control the obesity (fat content) of infants.

Breivik et al. teach a fatty acid composition comprising at least 80% by weight of omega-3-fatty acids, salts or derivatives thereof, wherein (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid comprises at least 75% by weight of the total fatty acids. The compositions can be used for the *treatment* [...] of multiple risk factors for cardiovascular diseases (abstract only).

Breivik et al. teach that present invention relates to a fatty acid composition comprising at least 80% by weight of omega-3 polyunsaturated fatty acids, wherein at least 75% by weight of the total fatty acids comprise omega-3 (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA) C 20:5 and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid (DHA) C 22:6 9column 1, lines 5-10).

Breivik et al. teach the same and exact preferred ratio limitation in the instant claims. The upgrading of the EPA fraction to obtain a weight ratio of EPA: DHA of from 1:1 to 2:1, especially 3:2 or the upgrading of the DHA fraction to obtain an EPA: DHA weight ratio of from 1:1 to 1:2 may be achieved in the molecular distillation stage. The method also provides the possibility of using supercritical fluid extraction and/or chromatography in the second stage with CO₂ eventually containing a more polar modifier, such as ethanol, in order to concentrate the EPA and/or DHA fraction (column 3, lines 61-67; column 4, lines 1 and 2).

Breivik et al. teach fish oil which is of animal origin (column 1, line 38). This limitation of oil also anticipates the limitation in the claims drawn to a liquid form (claim 51).

Breivik further renders obvious the claimed invention by teaching that this preferred ratio of EPA: DHA has an advantageous effect on risk factors for cardiovascular diseases (column 2, lines 50-67).

Breivik et al. teaches an esterified formulation comprising EPA: DHA (column 3, lines 2-39).

Breivik et al. does not go into specific detail as to risks of cardiovascular disease in view of the specific treatment thereof.

However, Corkey et al. essentially teach dietary products for infant child and adult nutrition which possess adequate levels and ratios of medium chain fatty acids and .omega.-polyunsaturated fatty acids. Consumption of these dietary products can contribute to the prevention of obesity in developing individuals and can contribute to a reduction in body fat mass in individuals who are trying to lose weight or reduce body fat mass (e.g., obese individuals). A first preferred product is a dairy supplement or formulated dairy product for consumption by infants or children to prevent development of obesity. A second preferred product is a **dietary supplement** for persons combating unwanted weight gain or obesity. Also featured are methods of formulating these dietary products (abstract only).

Corkey et al. teach a combination of MCFA and DHA Reduces Lipogenesis, Lipid Storage, and Secretion from Liver Cells (Please see example 12, paragraphs 121 and 122).

Corkey et al. teach dietary supplements and products aimed at preventing obesity, reducing fat mass, and/or reducing serum TGs (in particular, serum TGs associated with traditional MCT diets) [0006].

Corkey et al. teach [...]. Because the .omega.-3 long chain fatty acids (EPA:DHA) have been shown to efficiently inhibit fatty acid synthesis, it is proposed that mixing MCFA with a small portion of EPA and DHA will synergize the positive effects of both types of fatty acids in reducing fat storage in adipose tissue and fat product [0121].

Corkey et al. teach a dietary regimen to be incorporated concomitantly with the said weight-reduction formulation. The present invention features dietary supplements and products aimed at preventing obesity, reducing fat mass, and/or reducing serum TGs (in particular, serum TGs associated with traditional MCT diets) [0006]; [0034].

Corkey et al. teach a triglyceride form of the formulation. A glyceride is an ester of glycerol (1, 2, 3-propanetriol) with acyl radicals of fatty acids and is also known as an acylglycerol. If only one position of the glycerol molecule is esterified with a fatty acid, a "monoglyceride" is produced; if two positions are esterified, a "diglyceride" is produced; and if all three positions of the glycerol are esterified with fatty acid a "triglyceride" or "triacylglycerol" is produced. A glyceride is called "simple" if all esterified positions contain the same fatty acid; or "mixed" if different fatty acids are involved. The carbons of the glycerol backbone are designated sn-1, sn-2 and sn-3, with sn-2 being in the middle and sn-1 and sn-3 being the ends of the glycerol [0033].

Thus, it would be *prima facie* obvious to one of ordinary skill in the art to at once recognize a reasonable expectation of success via the incorporating together the methods and

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teachings of O'Connor et al., Breivik et al, and Corkey et al. Determining the scope and contents of the prior art in view of the immediate references *supra* has been reasonably assessed.

Consummately, the Breivik et al. reference teaches the current invention. The specificities drawn to a particular target population suffering from specific risks and disorders associated with cardiovascular diseases in need of such formulations are adequately supported and taught by Corkey et al. O' Connor et al. teach a higher percent concentration of DHA to EPA in obviousness over the claimed invention. Thus, in view of O'Connor et al., whether recognized or not, a method for at least treating obesity, overweight condition, weight reduction, etc. is fully contemplated and supported by O'Connor et al.

Accordingly, the level of ordinary skill in the pertinent art suggests well-known and well-established protocols which are sufficiently described, defined, and explained in the references above. As a result, the inventive objective of current invention is made obvious. In consideration of the objective evidence present in the current application, it would have been *prima facie* obvious to combine the references together in obviousness over the claimed invention.

In view of the differences, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to employ the fatty acid composition for treating persons with obesity because it is well-established in the art that the administration of such supplements aid in the treatment of weight control. Corkey et al. teach ratios of medium chain fatty acids and .omega.-polyunsaturated fatty acids. Further, the said reference teaches consumption of these dietary products [which] can contribute to the prevention of obesity in developing individuals and can contribute to a reduction in body fat mass in individuals who are

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trying to lose weight or reduce body fat mass (e.g., obese individuals). Accordingly, the reference of Corkey et al. reads on dietary formulations of the said fatty acids.

Similarly, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a dietary composition either in the form of a snack or emulsion. Accordingly, the reference of Corkey et al. reads on dietary formulations of which the said fatty acids are comprised.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY BETTON whose telephone number is (571)272-9922. The Examiner can normally be reached from Monday to Friday from 9am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627

Status of the Claims

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